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EXAMINER	
HIBBERT, CATHERINE S	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,419	LAFRENIERE ET AL.	
	Examiner	Art Unit	
	CATHERINE S. HIBBERT	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-55 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, 36-40, and 55, drawn to a method for identifying an agent that modulates the activity of an HSN2 gene, comprising contacting a test compound with a cell that expresses an HSN2 gene and determining a change in the expression of said gene as a result of said contacting.

Group II, claim(s) 9-17, drawn to a method for identifying an agent that modulates the activity of an HSN2 gene, comprising contacting a test compound with a construct comprising a reporter gene operably linked to an HSN2 promoter.

Group III, claim(s) 18-28, drawn to a method for identifying an agent that modulates the activity of an HSN2-encoded protein, comprising contacting a test compound with an HSN2-encoded polypeptide.

Group IV, claim(s) 29-34, drawn to a method of treating a pain-related/HSN2-related disorder.

Group V, claim(s) 35, drawn to a method of diagnosing the presence/risk of developing an HSN2-related disorder, the method comprising determining the presence of a mutation in the HSN2 gene or HSN2-encoded protein of an individual.

Group VI, claim(s) 41-47, drawn to an isolated polynucleotide.

Group VII, claim(s) 48-51, drawn to an isolated polypeptide.

Group VIII, claim(s) 52-54, drawn to a method for identifying an analgesic agent, the method comprising administering to an animal an agent found to modulate HSN2 activity.

The inventions listed as Groups 1-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of Invention is Lacking

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled *only* when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

In addition, as provided in 37 CFR 1.475(b), a national stage application

containing claims to different categories of invention will be considered to have unity of

invention if the claims are drawn only to one of the following combinations of categories

1) A product and a process specially adapted for the manufacture of said product; or
2) A product and process of use of said product; or
3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
4) A process and an apparatus or means specifically designed for carrying out the said process; or
5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

The special technical feature of the method of Group I is a cell that expresses the HSN2 gene.

The special technical feature of the method of Group II is an HSN2 promoter operably linked to a reporter.

The special technical feature of the method of Group III is contacting a test compound with an HSN2-encoded polypeptide.

The special technical feature of the method of Group IV is a method of treating a pain-related/HSN2-related disorder.

The special technical feature of the method of Group V is determining the presence of a mutation in the HSN2 gene or HSN2-encoded protein of an individual.

The special technical feature of the method of Group VI requires contacting a test compound with an HSN2-encoded polypeptide.

The special technical feature of Group VI is an HSN2 polynucleotide.

The special technical feature of Group VII is an HSN2 polypeptide.

The special technical feature of Group VIII is a method for identifying an analgesic agent, the method comprising administering to an animal an agent found to modulate HSN2 activity.

The technical feature that is common to all of the invention groups is a polynucleotide sequence related to the HSN2 gene. However, a polynucleotide sequence related to the HSN2 gene is not considered a special technical feature because Boyle et al (WO 01/57187 A, August 9, 2001 and Muzny et al (Database Genbank [Online] May 1 1999; XP002274931, Database accession no. AC004765) (both of record in the IPER) teach nucleic acids with 100% sequence identity relevant to SEQ ID NO: 5,1, 7,and 9 and therefore teach a polynucleotide sequence related to the HSN2 gene and therefore the common technical feature does not represent an advance over the prior art.

Requirement for Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If Applicants elect Group I,
-Applicant must further elect only one SEQ ID from among SEQ ID NOs: 1, 7 and 9 (corresponding to Claim 8); Claim 1 is generic.

-Applicant must further elect only one type of test compound from among small molecule, anti-sensorin antibody, antisense HSN2 nucleic acid molecule and HSN2 ribozyme (corresponding to Claims 37-40); Claim 36 is generic.

If Applicants elect Group III,
-Applicant must further elect only one nucleic acid SEQ ID from among SEQ ID NOs: 1, 7 and 9 (corresponding to Claim 27); and

-Applicant must further elect only one amino acid SEQ ID from among SEQ ID NOs: 2, 8, 10 and 11 (corresponding to Claim 28) that correlates to the nucleic acid SEQ ID elected from Claim 27); Claim 22 is generic.

If Applicants elect Group IV,
Corresponding to Claims 30 and 31,
-Applicant must further elect only one nucleic acid SEQ ID from among SEQ ID NOs: 1, 7 and 9 (corresponding to Claim 27 and Claim 8); and

-Applicant must further elect only one amino acid SEQ ID from among SEQ ID NOs: 2, 8, 10 and 11 (corresponding to Claim 28) that correlates to the nucleic acid SEQ ID elected from Claim 27); Claims 1 and 22 are generic.

If Applicants elect Group VI,
-Applicant must further elect only one nucleic acid SEQ ID from among SEQ ID NOs: 1, 6, 7 and 9 and 12 (corresponding to Claim 41); No claim is generic.

If Applicants elect Group VII,
-Applicant must further elect only one amino acid SEQ ID from among SEQ ID NOs: 2, 8, 10 and 11 and 13 (corresponding to Claim 48), no claim is generic.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species represented by different SEQ ID numbers are either different nucleic acid molecules or are different polypeptide molecules. The technical feature that is common to all of these species is a polynucleotide sequence related to the HSN2 gene. However, a polynucleotide sequence related to the HSN2 gene is not considered a special technical feature because Boyle et al (WO 01/57187 A, August 9, 2001 and Muzny et al (Database Genbank [Online] May 1 1999; XP002274931, Database accession no. AC004765) (both of record in the IPER) teach nucleic acids with 100% sequence identity relevant to SEQ ID NO: 5,1, 7,and 9 and therefore teach a polynucleotide sequence related to the HSN2 gene and therefore the common technical feature does not represent an advance over the prior art.

In addition, the following species: small molecule, anti-sensorin antibody, antisense HSN2 nucleic acid molecule and HSN2 ribozyme, do not share a technical feature that is common to all of these species. Specifically, a “small molecule” is generally considered to be a small biomolecule that is not a polymer and therefore are generally not considered to include proteins or large polynucleotides. In addition, the technical feature of a "small molecule" is not considered a special technical feature because “small molecules” are taught by Boyle et al (WO 01/57187 A, August 9, 2001) (e.g. growth factors listed on page 66, lines 4-8) and therefore the common technical feature does not represent an advance over the prior art.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE S. HIBBERT whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully submitted,

Catherine S. Hibbert
Examiner/AU1636

/Celine X Qian /

Primary Examiner, Art Unit 1636